

Appl. No. 09/926,002
Amendment dated: October 3, 2003
Reply to OA of: June 3, 2003

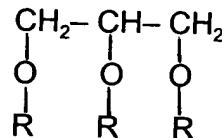
This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claim 1-10 canceled.

11(previously presented). A vaccine formulation against a mycobacterium comprising, as adjuvant, one or more substances selected from the group consisting of:

a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H, and

b) a fatty acid with 6 to 24 carbon atoms; and

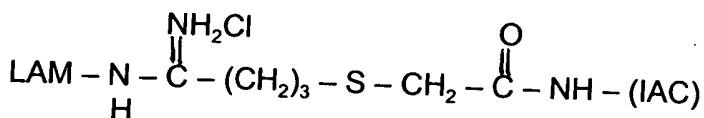
as immunizing component, an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bridge groups, to immunologically active carriers (IAC).

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12(previously presented). The vaccine formulation according to claim 11, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



13(currently amended). The vaccine formulation according to claim 11, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are derived from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria [[toxic]] toxoid, cholera subunit B or Protein D from *H. influenza*.

14(currently amended). The vaccine formulation according to claim 13, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms, and the immunologically active carriers (IAC) are derived [[form]] from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria [[toxic]] toxoid, cholera subunit B or Protein D from *H. influenza*.

15(previously presented). The vaccine formulation according to claim 11, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

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16(currently amended). The vaccine formulation according to claim 11, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is lipoarabinomannan-tetanus toxoid (LAM-TT).

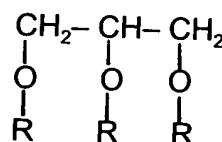
17(previously presented). The vaccine formulation according to claim 16, wherein the adjuvant further comprises soybean oil.

18(previously presented). The vaccine formulation according to claim 11, wherein the formulation is formulated into a preparation for mucosal administration.

19(previously presented). The vaccine formulation according to claim 18, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

20(Previously presented). An aerosol or spray package comprising a tuberculosis vaccine formulation comprising, as adjuvant, one or more substances selected from

a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H, and

b) a fatty acid with 6 to 24 carbon atoms, and

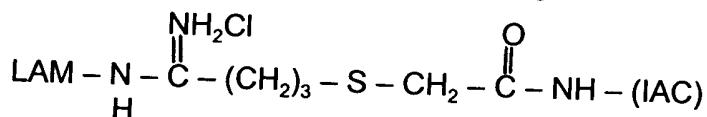
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as immunizing component, an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bridge groups, to immunologically active carriers (IAC).

21(previously presented). An aerosol or spray package according to claim 20, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



22(currently amended). An aerosol or spray package according to claim 21, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are derived from polypeptide and are selected from tetanus toxoid, diphtheria [[toxid]] toxoid, cholera subunit B or Protein D from *H. influenza*.

23(currently amended). An aerosol or spray package according to claim 22, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms, and the immunologically active carriers (IAC) are derived from polypeptide and are selected from tetanus toxoid, diphtheria [[toxid]] toxoid, cholera subunit B or Protein D from *H. influenza*.

24(previously presented). An aerosol or spray package according to claim 21, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure

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controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

25(previously presented). An aerosol or spray package according to claim 21, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is lipoarabinomannan-tetanus toroid (LAM-TT).

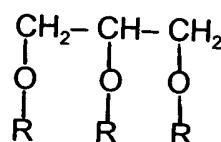
26(previously presented). An aerosol or spray package according to claim 21, wherein the formulation is formulated into a preparation for mucosal administration.

27(previously presented). An aerosol or spray package according to claim 26, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

28(previously presented). An aerosol or spray package according to claim 25, wherein the adjuvant further comprises soybean oil.

29(previously presented). A nose-drop package comprising a tuberculosis vaccine formulation comprising, as adjuvant, one or more substances selected from the group consisting of:

a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



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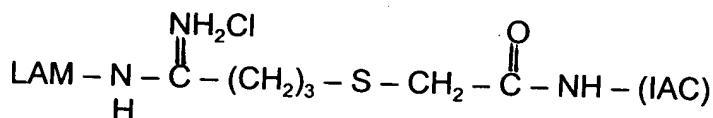
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wherein R is selected from H and an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H, and

b) a fatty acid with 6 to 24 carbon atoms; and

as immunizing component, an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bridge groups, to immunologically active carriers (IAC).

30(previously presented) The nose-drop package, according to claim 29, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



31(currently amended). The nose-drop package according to claim 29, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms, and the immunologically active carriers (IAC) are derived from polypeptide and are selected from tetanus toxoid, diphtheria [[toxic]] toxoid, cholera subunit B or Protein D from *H. influenza*.

32(previously presented). The nose-drop package according to claim 31, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms, and the immunologically active carriers

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(IAC) are derived from polypeptide and are selected from the group consisting of tetanus toxoid, diphtheria toxoid, cholera subunit B or Protein D from *H. influenza*.

33(previously presented) The nose-drop package according to claim 29, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

34(previously presented). The nose-drop package according to claim 29, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is lipoarabinomannan-tetanus toroid (LAM-TT).

35(previously presented). The nose-drop package according to claim 29, wherein the formulation is formulated into a preparation for mucosal administration.

36(previously presented). The nose-drop package according to claim 35, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

37(previously presented). The nose-drop package according to claim 34, wherein the adjuvant further comprises soybean oil.

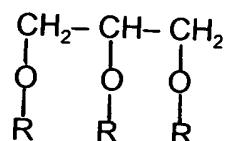
38(previously presented). A method of vaccinating a mammal against a mycobacterium having antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis*, which comprises mucosa administration to the mammal of a protection-inducing amount of a tuberculosis vaccine formulation comprising, as adjuvant, one or more substances selected from the group consisting of:

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a) monoglyceride preparations having at least 80% monoglyceride content and having a formula

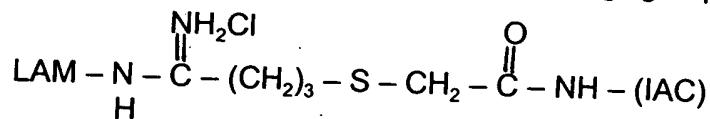


wherein R is selected from the group consisting of H and an acyl group containing from 6 to 24 carbon atoms with the proviso that two of the R groups are H; and

b) a fatty acid with 6 to 24 carbon atoms; and

as immunizing component, an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bridge groups, to immunologically active carriers (IAC).

39(previously presented). The method of vaccinating a mammal against mycobacterium according to claim 38, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



40(currently amended). The method of vaccinating a mammal against mycobacterium according to claim 38, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms and

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the immunologically active carriers (IAC) are derived from polypeptide and are selected from the group consisting of tetanus toroid toxoid, diphtheria [[toxid]] toxoid, cholera subunit B or Protein D from *H. influenza*.

41(previously presented). The method of vaccinating a mammal against mycobacterium according to claim 38, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms and the immunologically active carriers (IAC) are derived from polypeptide and are selected from tetanus toxoid, diphtheria toxoid, cholera subunit B or Protein D from *H. influenza*.

42(previously presented). The method of vaccinating a mammal against mycobacterium according to claim 38, wherein the vaccine further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

43(previously presented). The method of vaccinating a mammal against mycobacterium according to claim 38, wherein the monoglyceride preparation is monoolein and the fatty acid is oleic acid, and the immunizing component is lipoarabinomannan-tetanus toroid (LAM-TT).

44(previously presented). The method of vaccinating a mammal against mycobacterium according to claim 38, wherein the formulation is formulated into a preparation for mucosal administration.

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45(previously presented). The method of vaccinating a mammal against mycobacterium according to claim 44, wherein the mucosal administration is for nasal, pulmonary, oral or vaginal administration.

46(previously presented). The method of vaccinating a mammal against mycobacterium according to claim 43, wherein the adjuvant further comprises soybean oil.